

accent
bonding precision

REVIEWED

millibar, Vengaloor, 3/3/2023, 9:13:11 PM

QUALITY CONTROL CERTIFICATE OF ANALYSIS

Date: 16.02.2023

Product MICROCRYSTALLINE CELLULOSE USP **Batch No.:** 80230129
Grade ACCEL 112 **Mfg. Date:** February'2023
Party Name PT. MENJANGAN SAKTI **Re-evaluation Date:** January'2028
MOA USP/NF, JP, Ph. Eur., BP **Batch Qty:** 5000 Kgs.

Description White or almost white, practically insoluble in water, dilute acid and most of organic solvents, slightly soluble in dilute NaOH solution.

Pharmacopoeial test items	Batch Results	Specification
Identification A (Zinc Chloride test)	Passes	Have to correspond as USP/NF,JP,Ph.Eur.,BP
Identification B	Complies	NMT 350 as USP/NF,JP,Ph.Eur.,BP
(Degree of Polymerization)		
Solubility (coppertetramine solution)	Complies	Have to correspond as Ph. Eur.,BP
pH	6.46	5.0-7.5 as USP/NF,JP,Ph.Eur.,BP
Conductivity	47 $\mu\text{S.cm}^{-1}$	NMT 75 $\mu\text{S.cm}^{-1}$ as USP/NF,JP,Ph.Eur.,BP
Water - Soluble Substance	0.1634 %	NMT 0.25% as USP/NF,JP,Ph.Eur.,BP
Ether - Soluble Substance	0.0248 %	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	1.024 %	NMT 1.5 % as USP/NF,JP,Ph.Eur.,BP
Heavy Metals	Complies	NMT 10 PPM as USP/NF,JP,Ph.Eur.,BP
Residue on Ignition / Sulphated Ash	0.0548 %	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP

Standards	Batch Results	In house Specification
Bulk Density	0.3254 g/ml	0.26 to 0.50 g/ml
Assay (Dried)	98.64 %	97.0% to 102.0%
Sieve Analysis (% Retention)		
60 Mesh	0.32 %	$\leq 8.0\%$
200 Mesh	55.24 %	$\geq 45.0\%$
Particle Size Distribution		
D ₁₀	25 μ	$\leq 45 \mu$
D ₅₀	93 μ	70 - 100 μ
D ₉₀	201 μ	$\geq 140 \mu$

MICROBIAL LIMITS

Total Viable Aerobic Count	Complies	N.M.T. 1000cfu/g as USP/NF,JP,Ph.Eur.,BP
Total yeast & Mould Count	Complies	N.M.T 100cfu/g as USP/NF,JP,Ph.Eur.,BP
Staphylococcus aureus	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Escherichia Coli.	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Pseudomonas aeruginosa	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Salmonella species	Complies	Absent as USP/NF,JP,Ph.Eur.,BP

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph. - Eur<5.4>).

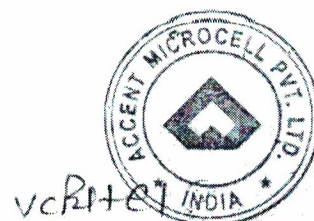
Storage recommendation: Preserve in tight containers.

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